

K103509

Page 1 of 4

MAY 19 2011

Unimax Medical Systems Inc.
510(k) Notification

Unimax Suction Irrigation Set

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Submitter: Unimax Medical Systems Inc.
Address: 8F-2, No. 127, Lane 235, Pao Chiao Rd., Hsin Tien City,
Taipei, Taiwan
Phone: 886-2-89191698
Fax: 886-2-89191528
Contact: Sophia Chiu
Establishment Registration Number: 3007791595

5.3 Identification of the Device:

Proprietary/Trade name: Unimax Suction Irrigation Set
Common Name: Suction Irrigation
Classification Name: Laparoscope, General & Plastic Surgery
Device Classification: II
Regulation Number: 876.1500
Panel: General & Plastic Surgery
Product Code: GCJ

5.4 Identification of the Predicate Device:

Predicate Device Name: GeniCon Laparoscopic Suction Irrigation
Manufacturer: Genicon
510(k) Number or Clearance Information: K041967

5.5 Intended Use and Indications for Use of the subject device.

The Unimax Suction Irrigation Set is available with an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.

K103509

Page 2 of 4

Unimax Medical Systems Inc.
510(k) Notification

Unimax Suction Irrigation Set

5.6 Device Description

The Unimax Suction Irrigation Set is indicated for use in patients undergoing a laparoscopic surgical procedure. It is designed to deliver-sterile irrigation fluids to surgical sites during laparoscopic procedures and to evacuate blood, tissue debris, and smoke from the surgical site.

The suction irrigation set consists of a hand piece equipped with two trumpet style valves, a probe, and connecting lines of tubing, one set designed to attach to a supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure.

The hand piece of the suction irrigator is designed to allow instruments to be introduced through the suction irrigation probe to reach the operative site. The instrument adapter is adjustable to allow a variety of instruments and diameters. It is a single use, disposable device and is sold sterile.

5.7 Non-clinical Testing

A series of in vitro and in vivo preclinical physical, mechanical and biocompatibility tests were performed to assess the safety and effectiveness of the Unimax Suction Irrigation Set. The tests were conducted in accordance with IEC 60601-2-2 Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment. All the test results demonstrate the performance of Unimax Suction Irrigation Set meets the requirements of its pre-defined acceptance criteria and intended uses.

The results of the non-clinical testing demonstrate that the Unimax Suction Irrigation Set is as safe and effective as the predicate devices.

5.8 Safety and Effectiveness

The result of bench testing indicates that the new device is as safe and effective as the predicate device.

K103509

Page 3 of 4

Unimax Medical Systems Inc.
510(k) Notification

Unimax Suction Irrigation Set

5.9 Substantial Equivalence Determination

The Unimax Suction Irrigation Set submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared GeniCon Laparoscopic Suction Irrigation which is the subject of K041967.

Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Item	Predicate Device (GeniCon Laparoscopic Suction Irrigation)	Proposed Device (Unimax Medical Systems Inc. Suction Irrigation Set)
Similarity		
Intended Use	The device is available with an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.	Same
Specification	The device consists of a hand piece equipped with two trumpet style valves, a probe, and connecting lines of tubing, one set designed to attach to a supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure. Reusable Monopolar Probe: Description Size	Same

K103509

Page 4 of 4

Unimax Medical Systems Inc.
510(k) Notification

Unimax Suction Irrigation Set

	Spatula Probe 5mm x 33cm J-Hook Probe 5mm x 33cm L-Hook Probe 5mm x 33cm	
Biocompatibility	Cytotoxicity test Intracutaneous test Maximization sensitization test	Same

5.10 Conclusion

After analyzing bench tests, electrical safety testing data, it can be concluded that Unimax Suction Irrigation Set is as safe and effective as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

MAY 19 2011

Unimax Medical Systems, Inc.
% AcmeBiotechs Co., Ltd.
Mr. Michael Lee
No. 45, Minsheng Rd., Danshui Town
Taipei County, 251 Taiwan

Re: K103509
Trade/Device Name: Unimax Suction Irrigation Set
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 25, 2011
Received: April 25, 2011

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

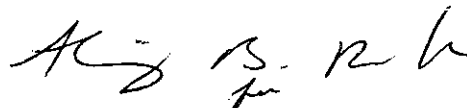
Page 2 – Mr. Michael Lee

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103509

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Indications for Use

510(k) Number (if known):

Device Name: Unimax Suction Irrigation Set

Indications for Use:

The Unimax Suction Irrigation Set is available with an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nail AP Ozden for mcm
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

Page 1 of 1

510(k) Number K103509